

CLAIMS

What is claimed is:

- 5 1. A stable isolated nucleic acid reference standard, said nucleic acid reference standard comprising an isolated target nucleic acid comprising a known sequence wherein said isolated target nucleic acid is bound with a microparticulate binding agent, and wherein when said isolated target nucleic acid is so bound said isolated target nucleic acid is not substantially detected in a nucleic acid assay.
- 10 2. The isolated nucleic acid reference standard of claim 1, wherein said binding agent is at least one of a binding agent selected from the group consisting of a liposome, a polyamine, a siliceous compound, a zeolite, a polystyrene, chitin, and chitosan.
- 15 3. The isolated nucleic acid reference standard of claim 2, wherein said polyamine is nylon.
- 20 4. The isolated nucleic acid reference standard of claim 2, wherein said polystyrene is selected from the group consisting of an amine modified polystyrene and a carboxy polystyrene.
- 25 5. The isolated nucleic acid reference standard of claim 2, wherein said siliceous compound is selected from the group consisting of silica gel, fumed silica, a glass particle, diatomaceous earth, and an amine-modified silica.
6. The isolated nucleic acid reference standard of claim 2, wherein said zeolite is low alumina zeolyte.

7. The isolated nucleic acid reference standard of claim 1, where said binding agent is mixed with a solution selected from the group consisting of a solution comprising alcohol, a solution comprising oil, and a solution comprising a wax base.

5 8. The isolated nucleic acid reference standard of claim 1, wherein said isolated target nucleic acid comprises a known sequence selected from the group consisting of a ribonucleic acid and a deoxyribonucleic acid.

10 9. The isolated nucleic acid reference standard of claim 8, wherein said isolated target nucleic acid comprises a known sequence selected from the group consisting of a linear nucleic acid and a non-linear nucleic acid.

15 10. The isolated nucleic acid reference standard of claim 1, wherein said nucleic acid reference standard is used to assess the proficiency of a nucleic acid assay.

20 11. A stable isolated nucleic acid reference standard, said nucleic acid reference standard comprising an isolated target nucleic acid comprising a known sequence wherein said isolated target nucleic acid is bound with a microparticulate binding agent, and wherein when said isolated target nucleic acid is so bound said isolated nucleic acid is not substantially detected in a nucleic acid assay.

25 12. A method of assessing the proficiency of a nucleic acid assay, said method comprising
a) obtaining a test sample;
b) preparing a nucleic acid reference standard comprising a target nucleic acid comprising a known nucleic acid sequence and a binding agent;
c) assessing the presence or absence of a second nucleic acid in said test sample using a nucleic acid assay; and

d) assessing the presence or absence of said known nucleic acid in said nucleic acid reference standard using the nucleic acid assay of (c),

wherein detection of said known nucleic acid sequence in (d) is an indication that said nucleic acid assay is proficient.

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13. The method of claim 12, wherein said nucleic acid reference standard is mixed with said test sample and the presence or absence of said known nucleic acid and the presence or absence of said second nucleic acid in said test sample are assessed.

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14. A method of producing a stable isolated nucleic acid reference standard, said reference standard comprising an isolated target nucleic acid comprising a known sequence wherein said isolated nucleic acid is bound with a microparticulate binding agent, and further wherein when said isolated nucleic acid is so bound said isolated target nucleic acid is not substantially detected in a nucleic acid assay, said method comprising contacting said isolated target nucleic acid with said microparticulate binding agent, thereby producing a stable isolated nucleic acid reference standard.

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15. The method of claim 14, wherein said microparticulate binding agent is at least one of a binding agent selected from the group consisting of a liposome, a polyamine, a siliceous compound, a zeolite, a polystyrene, chitin, and chitosan.

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16. The method of claim 15, wherein said polyamine is nylon.

17. The method of claim 15, wherein said polystyrene is selected from the group consisting of an amine modified polystyrene and a carboxy polystyrene.

18. The method of claim 15, wherein said siliceous compound is selected from the group consisting of silica gel, fumed silica, a glass particle, diatomaceous earth, and an amine-modified silica.

5 19. The method of claim 15, wherein said zeolite is low alumina zeolyte.

20. The method of claim 14, where said binding agent is mixed with a solution selected from the group consisting of a solution comprising alcohol, a solution
10 comprising oil, and a solution comprising a wax base.

21. The method of claim 14, wherein said isolated target nucleic acid comprising a known sequence is selected from the group consisting of a ribonucleic acid and a deoxyribonucleic acid.
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22. The method of claim 14, wherein said isolated target nucleic acid comprising a known sequence is selected from the group consisting of a linear nucleic acid and a non-linear nucleic acid.

20 23. A kit for assessing the proficiency of a nucleic acid assay, said kit comprising a nucleic acid reference standard of claim 1, said kit further comprising an applicator, and an instructional material for the use thereof.

24. A kit for producing a nucleic acid reference standard, said kit
25 comprising an isolated target nucleic acid comprising a known sequence and a binding agent, said kit further comprising an applicator, and an instructional material for the use thereof.

25. The kit of claim 24, wherein said binding agent is at least one of a binding agent selected from the group consisting of a liposome, a polyamine, a siliceous compound, a zeolite, a polystyrene, chitin, and chitosan.

5 26. The kit of claim 25, wherein said polyamine is nylon.

27. The kit of claim 25, wherein said polystyrene is selected from the group consisting of an amine modified polystyrene and a carboxy polystyrene.

10 28. The kit of claim 25, wherein said siliceous compound is selected from the group consisting of silica gel, fumed silica, a glass particle, diatomaceous earth, and an amine-modified silica.

15 29. The kit of claim 25, wherein said zeolite is low alumina zeolyte.

30. The kit of claim 24, said kit further comprising a solution selected from the group consisting of a solution comprising alcohol, a solution comprising oil, and a solution comprising a wax base.

20 31. The kit of claim 24, wherein said isolated target nucleic acid comprising a known sequence is selected from the group consisting of a ribonucleic acid and a deoxyribonucleic acid.

25 32. The kit of claim 24, wherein said isolated target nucleic acid comprising a known sequence is selected from the group consisting of a linear nucleic acid and a non-linear nucleic acid.